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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,789	11/08/2001	C. Frank Bennett	RTS-0333	4716

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EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 05/21/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/008,789	Applicant(s) BENNETT ET AL.	
	Examiner Terra C. Gibbs	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,12-15,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,12-15,19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Office Action is a response to the Amendment filed March 11, 2003, in Paper No. 8.

#### ***Response to Amendment***

Claims 11 and 16-18 have been canceled. Claims 1 and 15 have been amended.

Claims 1, 2, 4-10, 12-15, 19 and 20 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 15, 19 and 20 under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims is withdrawn in view of Applicant's arguments.

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Schneider (2001) is withdrawn in view of Applicant's arguments.

The rejection of claims 1, 2, 4-10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (Forschungszentrum Karlsruhe, 2001, FZKA 6587, 1-139) in further view of Baracchini et al. [U.S. Patent No. 5801154] and Fritz et al. (Journal of Colloid

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and Interface Science, 1997 Vol. 195:272-288) is maintained for the reasons of record set forth in the Office Action mailed September 11, 2002 in Paper No. 5.

Applicants, in response to the previous Office Action, argue that the claims (as amended) recite specific regions within thyroid hormone receptor interactor 6 (SEQ ID NO: 3) that are not taught in the primary reference of Schneider et al. Applicants also argue that Schneider et al. disclose the general use of antisense for inhibition of expression of thyroid hormone receptor interactor 6, but do not teach specific active sites/regions of thyroid hormone receptor interactor 6 that may be targeted by antisense. Applicants also argue that Baracchini et al. teach modifications to antisense oligonucleotides to enhance activity, but do not teach or suggest the use of antisense compounds targeted to specific regions of thyroid hormone receptor interactor 6. Applicants further argue that Fritz et al. disclose cationic polystyrene nanoparticles as carrier systems for antisense compounds in general, but do not teach or suggest the use of antisense compounds targeted to specific regions of thyroid hormone receptor interactor 6.

Applicant's argument has been carefully considered but are not considered persuasive. Applicant argues against the references individually, but must consider the rejection based upon the combination of the references. *See*, MPEP 2145. As argued in the Office action mailed September 11, 2002, it would have been *prima facie* obvious to make antisense oligonucleotides encoding thyroid hormone receptor interactor 6 (Trip6) since the prior art has asserted that it is of considerable interest to investigate the possible role of Trip6 in human cancers (Yi and Beckerle). As further argued, one of ordinary skill in the art would have had a reasonable expectation of success in making antisense oligonucleotides targeting thyroid hormone receptor interactor 6 since Schneider taught the reduction of endogenous Trip6 protein by antisense

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techniques. As further argue, one of ordinary skill in the art would have been motivated to modify antisense oligonucleotides since the prior art has taught the desirability of such oligonucleotides are often preferred over native forms because of enhanced cellular uptake, enhanced affinity for nucleic acid target, increased stability in the presence of nucleases and the exhibition of high colloidal stability with low toxic side effects as required for biological experiments (Baracchini et al. and Fritz et al.).

Further, regarding a compound 8 to 50 nucleobases in length targeted to a 5'-untranslated region, a start codon region, a coding region, or a 3'-untranslated region of a nucleic acid encoding thyroid hormone receptor interactor 6 of SEQ ID NO: 3, as now recited in amended claim 1 and Applicant's arguments that Schneider et al. do not disclose specific regions within thyroid hormone receptor interactor 6 that may be targeted by antisense and Baracchini et al and Fritz et al. do not teach the use of antisense compounds targeted to specific regions of thyroid hormone receptor interactor 6, Baracchini et al. teach antisense oligonucleotides that can specifically hybridize with a 5'-untranslated region, a start codon region, a coding region, or a 3'-untranslated region of a target gene (see column 9, lines 6-67 and column 10, lines 1-25 and Table 1). Thus, one of ordinary skill in the art would have been motivated and expected success to make an antisense compound targeting specific regions such as the 5'-untranslated region, the start codon region, a coding region, or the 3'-untranslated region nucleic acid molecule encoding thyroid hormone receptor interactor 6 because it is well known in the art to target different sites/regions within a gene for the oligonucleotide interaction to occur such that a desired effect (e.g., detection or modulation of expression of the protein) will result.

***Claim Objections***

Claims 1, 2, 4-10, 12-15, 19 and 20 are objected to for the following informalities(s):

Claim 1 and its dependent claims 2, 4-10, 12-15, 19 and 20 recite, "a compound 8 to 50 nucleobases in length targeted to a 5'-untranslated region, a start codon region, a coding region, or a 3'-untranslated region of a nucleic acid molecule of SEQ ID NO: 3 encoding thyroid hormone receptor interactor 6". The use of the article "a" in lines 2-3 of claim 1 is improper since all the limitations are drawn to the nucleic acid. Replacement with the language "the" in lines 2-3 of claim 1 would overcome the instant rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-10, 12-15, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4-10, 12-15, 19 and 20 are indefinite because they recite or depend from the term "compound". The term "compound" is a relative term which renders the claim indefinite. The term "compound" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Replacement with the language "antisense nucleic acid" would overcome the instant rejection.

Claim 19 is indefinite because it recites the term “differentially inhibits”. The term “differentially inhibits” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the term “differentially inhibits”.

Claim 19 is indefinite because it recites, “The compound of claim 1 targeted to a nucleic acid molecule encoding thyroid hormone receptor interactor 6, wherein said compound specifically hybridizes with and differentially inhibits the expression of one or more of the variants of thyroid hormone receptor interactor 6 relative to the remaining variants of thyroid hormone receptor interactor 6”. It is unclear what is meant by “relative to the remaining variants of thyroid hormone receptor interactor 6”. Appropriate correction is required.

Claim 20 is indefinite because it recites the term “TRIP-6I”. The term “TRIP-6I” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the term “TRIP-6I”.

### ***Conclusion***

No claims are allowable


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg  
May 6, 2003

  
**RAM SHUKLA**  
**PRIMARY EXAMINER**